

Disposal of Controlled Substances Overview

Options Available for Disposal

1. Take-back events
 - Law Enforcement Only
2. Mail-Back Programs
 - Must be from an authorized collector that has and utilizes an on-site method of destruction – excluding law enforcement
3. Collection Receptacle Locations
 - Various locations

Take-Back Events

- Law Enforcement only, however MAY partner with private entities
- SHALL appoint a law enforcement officer who
 - Is employed full time by the agency
 - Be under the direction and control of the federal, state, tribal, or local government and be acting in the course of their official duty
 - Be duly sworn and given the authority to
 - Carry firearms
 - Execute and serve warrants
 - Make arrests without warrants
 - Make seizures of property
 - This officer will maintain control and custody of CS from time collected to secure transfer or destruction
- Only the end user (or person lawfully entitled) may transfer CS to the law enforcement agency.
- No other person (Ex. Volunteer) may touch or handle CS at any time

Mail-Back Program

- Must be from an authorized collector that has and utilizes an on-site method of destruction (law enforcement agency excluded)
- Must provide specific packages (no cost or at a charge) to ultimate users for collection of controlled substances
- May partner with a third party.
 - Example: Authorized collector with on-site destruction method (such as a reverse distributor) produces a mail-back package which is then sold at retail pharmacy. Reverse distributor is the operator of the mail-back program, and is responsible for recordkeeping and security.
- Packages must be received at registered site where destruction occurs

Mail-Back Packaging Regulations

- Mail-Back Package requirements:
 - Postage-paid (business reply)
 - Pre-addressed
 - Non-descript
 - Tamper-evident
 - Tear-resistant
 - Marked with a unique identification number
 - Include user instructions describing what substances are permitted to be included in the package
 - No personal identification
- No requirements for collectors to create and maintain a notification system, but is not prohibited
- May receive packages from any location within the United States

Collection Receptacles

- May not be placed at non-registered sites
- Must be securely fastened to a permanent structure
- Pharmacy staff shall not handle controlled substances from ultimate users. Controlled substances must be placed in collection receptacles by the ultimate user.
- Must have sign that indicates only Schedule II-V controlled substances and non-controlled substances are accepted. Must clearly indicate that Schedule I and illicit or dangerous substances are not allowed to be placed in receptacle.
- Physical Collection Receptacles must have a permanent outer container with removable inner liner.
- Outer Container must have an opening big enough to allow contents to be added to the inner liner but small enough to prevent removal of inner contents
 - Opening must be capable of being locked at times when employee is not present unless receptacle is located in a secured area of a LTCF which is regularly monitored
 - No markings or symbols required
- Inner Lining must be:
 - Waterproof
 - Tamper-evident
 - Tear-resistant
 - Removable and sealable immediately upon removal without emptying or touching contents
 - Marked with a unique identification number that enables tracking
 - Clearly marked with liner size (i.e., 5 Gallon)

<p>Who can be an Authorized Collector?</p>	<ul style="list-style-type: none"> ▪ A Registered <ul style="list-style-type: none"> ○ Manufacturer ○ Distributor ○ Reverse Distributor ○ Retail Pharmacy ○ Narcotic Treatment Program ○ Hospital or Clinic with on-site pharmacy ○ Retail pharmacies ▪ Must be registered with DEA for Schedule II controlled substances
<p>Disposal of Collection Receptacles (Registered Practitioners)</p>	<ul style="list-style-type: none"> • Promptly destroy the sealed inner liners and contents using on-site method of destruction in accordance with Subpart C of part 1317. • Promptly deliver the sealed inner liners and their contents by common or contract carrier to the registered location of a reverse distributor or distributor for destruction, or by reverse distributor pick-up at collector's registered or authorized location • Request assistance from the Special Agent in Charge of the Administration in the area in which the practitioner is located by submitting one copy of DEA Form 41 identifying what is to be disposed.
<p>Disposal of Collection Receptacles (Non-Registered Practitioners)</p>	<ul style="list-style-type: none"> • Promptly destroy the sealed inner liners and their contents using an on-site method of destruction in accordance with Subpart C of part 1317. • Promptly deliver the sealed inner liners and their contents by common or contract carrier to the registered location of a reverse distributor or distributor, or by reverse distributor pick-up at the collector's registered or authorized location. • Promptly transport the sealed inner liners and their contents by the collector's own means to the registered location of a reverse distributor or distributor, or to the location of destruction.
<p>Long Term Care Facilities and Collection Receptacles</p>	<ul style="list-style-type: none"> ▪ Only a hospital/clinic with an on-site pharmacy or a retail pharmacy that receives authorization to collect at a specific LTCF may manage and collect receptacles at that LTCF or remove or supervise removal of the inner liner ▪ Those pharmacies must modify their registration and include the physical locations of each LTCF at which they intend to operate a collection receptacle ▪ The Collection Receptacle must be located in a secured area monitored by employees of the LTCF ▪ Access to inner liner is restricted to employees of the

	<p>authorized collector</p> <ul style="list-style-type: none"> ▪ Two authorized employees of the authorized collector must remove or supervise removal of inner liner, or the LTCF may designate a supervisor-level employee to install, remove, store, or transfer inner liners with only one employee of the authorized collector ▪ May store sealed inner liners upon removal from a collection receptacle at LTCFs in securely locked, substantially constructed cabinet or securely locked room with controlled access for up to three business days until liners can be transferred for destruction ▪ LTCF are permitted to dispose of controlled substances on behalf of ultimate users who resided at the LTCF ▪ May store sealed inner liners upon removal from a collection receptacle at LTCFs in r have resided in that LTCF <ul style="list-style-type: none"> ○ Must transfer immediately but no longer than 3 business days after ultimate user no longer needs, wants, or discontinues use of CS
Methods of Destruction	<ul style="list-style-type: none"> ▪ Make non-retrievable → Standard of destruction ▪ Current examples include <ul style="list-style-type: none"> ○ Incineration ○ Chemical digestion ▪ Kitty litter or flushing do not meet standards <ul style="list-style-type: none"> ○ Does not apply if ultimate user is disposing of own medications ▪ No preferred method as long as it meets standard and complies with all applicable current laws
Non-Retrievable	<ul style="list-style-type: none"> ▪ To permanently alter any controlled substance's physical and/or chemical state through irreversible means in order to render that controlled substance unavailable and unusable for practical purposes ▪ Render substance no longer susceptible to diversion for an illicit or non-medical use
Return and Recall	<ul style="list-style-type: none"> ▪ May return substance for purpose of return/recall to: <ul style="list-style-type: none"> ○ The registered person from whom it was obtained ○ The registered manufacturer of the substance ○ Another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf

Ultimate User Product Recall	<ul style="list-style-type: none"> ▪ The ultimate user may return a recall product to: <ul style="list-style-type: none"> ○ The manufacturer of the recalled controlled substance ○ Another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf ▪ Entity DOES NOT need to be an authorized collector ▪ Must report all recalled controlled substance acquisition transactions either individually or overall
Security Measures for Collection through Mail-Back and Collection Receptacle Programs	<ul style="list-style-type: none"> ▪ Sealed mail-back packages and inner liners acquired by authorized collectors and registered reverse distributors and distributors must be stored in a manner consistent with the physical security requirements for Schedule II controlled substances ▪ May not distribute mail-back packages or inner liners through non-controlled stock ▪ All losses or theft from a collection receptacle or mail-back program must be reported to the DEA
Narcotic Treatment Programs Special Requirements	<ul style="list-style-type: none"> ▪ Higher security measures are required due to increased risk ▪ Collection receptacles must be in a room that does not contain any other controlled substance, is securely locked, and has controlled access
Hospitals/Clinics With On-Site Pharmacy Special Requirements	<ul style="list-style-type: none"> ▪ Must place collection receptacles in the immediate proximity of a location where it would be regularly monitored by employees ▪ May not be in proximity of any area where emergency or urgent care is provided
Record Keeping: Destruction	<ul style="list-style-type: none"> ▪ Shall maintain a record of destruction on DEA Form 41 <ul style="list-style-type: none"> ○ Include name and signature of two employees that witnessed destruction

Record Keeping: Reverse Distributor Return/Recall

- Date of receipt
- Name and quantity of each controlled substance received
- Name, address, and registration number of the person from whom the substance was received
- Reason for return
- Date of return to the manufacturer or other registrant authorized by the manufacturer to accept returns on their behalf
 - Name and quantity of each controlled substance returned
 - Name, address, and registration number of person from whom the substance was received
 - Name, address, and registration number of the registrant to whom the substance was returned
 - Method of return

Record Keeping: Reverse Distributor

- For each sealed inner liner acquired from an authorized collector or law enforcement, and for each sealed mail-back package acquired from law enforcement:
 - Date of acquisition
 - Number and size (size only for sealed inner liners)
 - Unique identification number of each sealed inner liner and mail-back package
 - Name, address, and for registrants, the registration number of the person from whom the sealed inner liners and mail-back packages were received
- Destruction
 - Date, place, and method of destruction
 - Number of sealed inner liners and mail-back packages destroyed
 - Name, address, and for registrants, the registration number of the person from whom the sealed inner liners and mail-back packages were received
 - Number size of all sealed inner liners and mail-back packages destroyed
 - Unique identification number of each sealed inner liner and sealed mail-back package destroyed
 - Name and signature of two employees that witnessed the destruction
- Record of receipt shall be maintained together with the corresponding record of return or destruction (DEA Form 41)

Record Keeping: Authorized Collectors

- Mail-Back Program
 - Date of the inventory
 - Number of mail-back packages
 - Unique identification number of each package on hand and whether unused or awaiting destruction
- Collection Receptacles
 - Date of inventory
 - Number and size of inner liners (5/10 gallon)
 - Unique identification number of each liner
- Mail-Back Packages
 - Unused packages that the authorized collector makes available to ultimate users and other authorized non-registrants at the collector's registered address.
 - Date made available
 - Number of packages
 - Unique identification number of each package
 - For unused packages provided to a third party to make available to ultimate users
 - Name of third party and physical address of the location receiving the packages
 - Date sent
 - Number of unused packages sent and corresponding unique identification numbers
 - Sealed mail-back packages received by the collector
 - Date of receipt
 - Unique identification number on each package
 - For packages destroyed on-site
 - Number of sealed mail-back packages destroyed
 - Date and method of destruction
 - Unique identification number of each mail-back package destroyed
 - Names and signatures of two employees who witnessed destruction
- Collection Receptacle Inner Liners
 - Date inner liner acquired
 - Unique identification number and size of each unused inner liner acquired, installed, removed, or transferred for destruction
 - Date each inner liner is installed
 - Physical address/location where each inner

liner is installed

- Registration number of the authorized collector
 - Name and signatures of two employees that witnessed installation, removal, or transfer for destruction
 - Date each inner liner is removed and sealed
 - Address of the location from which each inner liner is removed
 - Date each sealed inner liner is transferred for destruction
 - Address and registration number of the reverse distributor or distributor to whom each sealed inner liner was transferred
- If destroyed on-site by authorized collector, record same information required of reverse distributor